

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in April 2016.

Sponsor Change

NADA Number: 141-070

Previous Sponsor: Bayer HealthCare LLC, Animal Health Division
New Sponsor: iVaoes Animal Health
Drug Labeler Code: 86064

Suitability Petition

Number: 16-P-0134

Petitioner: Summit Pharmaceuticals Inc.
Date Filed: January 20, 2016
Action: Denied
Action Date: April 8, 2016
Description: The petitioner requested to file an ANADA for a generic phenylbutazone paste for use in horses that differs from the pioneer product, EQUIZONE Powder, sponsored by A & G Pharmaceuticals, Inc. under ANADA 200-334. The proposed change is in dosage form, the method of dispensing and flavoring. The RLNAD is approved as a powder in a jar, and is citrus flavored. The proposed change is to a paste, in a 60 mL dial-a-dose syringe and apple flavoring.